DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

3/3/98

14636

February 18, 1998

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-16-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Douglas R. Block
Hunter Haven Farms
17990 IL Rte 73
Pearl City, IL 61062

Dear Mr. Block:

An investigation of your cattle raising and shipping operation conducted by Investigator Chad E. Schmear on December 18 and 30, 1997, confirmed that you offered a dairy cow for sale for slaughter as human food in violation of Section 402(a)(2)(D) and Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about November 5, 1997, you sold a dairy cow for slaughter as human food to [ ] USDA analysis of tissue samples collected from the animal identified the presence of 4.50 parts per million (ppm) sulfadimethoxin in the muscle tissue, and 3.30 ppm of sulfadimethoxin in the liver. The established Regulatory Action levels for sulfadimethoxin in cattle is 0.10 ppm. The presence of this drug in the edible tissue from this animal causes the food to be adulterated under Section 402(a)(2)(D) of the Act.

A food is also deemed to be adulterated under Section 402(a)(4) if it has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies to your case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possible harmful drug residues are likely to enter the food supply. Our investigation found you used the drug in a manner which was contrary to the directions contained in the labeling, and thereby altered the labeled withdrawal period.

The above is not intended as an all-inclusive list of violations. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

You should take prompt action to correct these violations and establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes official notification under the law.

Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Paul A. Boehmer, Compliance Officer.

Sincerely,

Raymond V. Mlecko
District Director

cc: Manzoor Chaudry, D.V.M.
USDA Technical Service Center
106 South 15th St., Ste 904
Omaha, NE 68102

cc: Richard Hull, D.V.M.
Chief Veterinarian
Bureau of Animal Health
Div. Of Animal Industries
IL Dept. Of Agriculture
PO Box 19281
Springfield, IL 62794-9281

cc: Mark Ringler, Bureau Manager
Bureau of Agricultural Products Inspection
Div. Of Agricultural Industry Regulations
IL Dept. of Agriculture
PO Box 19281
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